IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

TEXAS MEDICAL ASSOCIATION, *et al.*, Plaintiffs, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Civil Action No. 6:22-cv-00372-JDK Lead Consolidated Case

DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN OPPOSITION TO PLAINTIFFS' SUMMARY JUDGMENT MOTIONS

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For the reasons stated below, the Defendants respectfully request that the Court award summary judgment in their favor.

INTRODUCTION

The harms of surprise medical bills are well documented and undisputed. In an emergency, for example, a patient might be given care by a provider who, through no fault of the patient, is outside the "network" of providers under the patient's health plan or health insurance issuer. Or a patient might carefully schedule a procedure at an in-network facility but, unbeknownst to him or her, a portion of the service could be performed by an out-of-network provider. Such cases have often led to staggering, and sometimes ruinous, medical bills. This phenomenon of surprise billing has also affected health care costs overall, driving up in-network care expenses and insurance premiums.

Congress enacted the No Surprises Act ("NSA" or the "Act") to curb this surprise billing problem. The Act limits a patient's share of the cost of emergency services delivered by out-of-network providers and facilities, services delivered by out-of-network air ambulance providers, and non-emergency services provided by certain out-of-network providers at in-network facilities absent patient consent. The Act also addresses how a payment dispute in these situations between an out-of-network provider or facility and a group health plan or health insurance issuer will be resolved. The Act creates an arbitration mechanism whereby each party submits its proposed payment amount, and an independent, private arbitrator selects between the two offers. Congress also directed the Departments of Health and Human Services, Labor, and the Treasury (the "Departments")—the Defendants in this suit—to create rules governing the arbitration process (the independent dispute resolution or "IDR" process) under which the arbitrator ("certified IDR entity") determines which offer to select.

To carry out Congress's mandate, the Departments exercised their rulemaking authority to issue rules guiding the arbitrators in their selection of an offer. They first issued an interim final rule that instructed the arbitrator to defer to the "qualifying payment amount"—a rough proxy for the fair market value of any given item or service—unless credible information countered otherwise. Last year, Plaintiffs here challenged that interim final rule, and this Court agreed with them, striking from the

interim final rule those provisions that were found to impose a "presumption in favor of the offer closest to the [qualifying payment amount.]" *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.* ("*TMA I*"), 587 F. Supp. 3d 528, 540 (E.D. Tex. 2022); *see also LifeNet, Inc. v. U. S. Dep't of Health & Hum. Servs.* ("*LifeNet I*"), No. 6:22-CV-162-JDK, 2022 WL 2959715 (E.D. Tex. July 26, 2022).

Taking this Court's opinions to heart, the Departments promulgated a final rule that eliminated the language this Court viewed as creating a presumption in favor of the qualifying payment amount. The final rule set forth a new standard: it instructs the arbitrator to consider all of the permissible information submitted and to select the offer that best represents the value of the item or service at issue in the dispute. The final rule makes clear that arbitrators are not required to defer to the qualifying payment amount, and the parties remain free to argue to the arbitrator that the qualifying payment amount does not represent the value of the item or service.

But reading Plaintiffs' briefs, one would not know the actual standard the final rule imposed, because Plaintiffs never mention it. Indeed, they do not challenge the key provision instructing the arbitrator which offer to select. Instead, for dozens of pages, Plaintiffs tilt at windmills in an attempt to find in the final rule the same presumption in favor of the qualifying payment amount that was in the interim final rule and which the Departments have now expressly and repeatedly disavowed. Plaintiffs are thus left to focus on various ancillary, evidentiary, and procedural portions of the final rule, contending that those provisions functionally reimpose the very presumption this Court previously struck down. But those provisions, either in isolation or cumulatively, do no such thing.

Plaintiffs challenge provisions instructing the arbitrator not to give weight to information that is not credible or not relevant to the dispute, and not to give extra weight to information that is accounted for twice. They also take issue with the fact that the arbitrator is not instructed to re-open the calculation of the qualifying payment amount to verify its accuracy. Plaintiffs' challenge fails, for multiple reasons. To start, Plaintiffs offer nothing but speculation to show that these provisions injure them in any way or ultimately determine which offer of payment the arbitrator should select—much less that, whether separately or together, these provisions effectively reimpose the presumption that this Court previously found to give them standing. In any event, even if this Court were to reach the

merits, the challenged portions of the final rule represent the kind of reasonable evidentiary and procedural rules governing adjudications that agencies are authorized to establish and that are entitled to deference.

The final rule, including the portions Plaintiffs challenge, furthers Congress's clear command to establish an efficient IDR process, and ensures that arbitrators approach payment disputes in a consistent and predictable manner, lowering administrative costs and promoting earlier settlement, eventually passing those savings along to payers, providers, and ultimately patients. This Court should grant summary judgment to Defendants.

STATEMENT OF THE ISSUES

1. Have the Plaintiffs met their burden to establish Article III standing, where they have provided no concrete evidence that the challenged portions of the final rule will harm them?

2. Did the Departments reasonably exercise the rulemaking authority that Congress granted them in the No Surprises Act by establishing a process whereby an arbitrator, in setting a payment amount for an out-of-network medical service, will select the offer that best represents the value of the qualified IDR item or service and not give weight to information that is not credible, not relevant, or already accounted for in the information before the arbitrator?

STATEMENT OF UNDISPUTED MATERIAL FACTS

I. Providers' Surprise Billing Practices Have Imposed Devastating Financial Consequences on Patients and Have Driven Up the Overall Cost of Health Care.

Most health plans and health insurance issuers "have a network of providers and health care facilities (participating providers or preferred providers) who agree by contract to accept a specific amount for their services." *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872, 36,874 (July 13, 2021) (AR 000166). When an individual receives care from a provider or facility outside of their plan's or insurer's network, however, the plan or insurer could decline to pay for the services, or could pay an amount lower than the provider's billed charges, leaving the patient responsible for the balance of the bill. *Id.* This practice, where the provider bills the patient for the difference between

the charges the provider billed and the amount paid by the patient's health plan, is known as balance billing.

"A balance bill may come as a surprise for the individual." *Id.* Surprise billing occurs, for example, when a patient receives care from a provider whom the patient could not have chosen in advance, or whom the patient did not have reason to believe would be outside the network of the patient's insurance plan. *Id.* These bills have arisen most frequently in three circumstances. First, in emergency situations, a patient may be unable to choose which emergency department he or she goes to (or is taken to); even if the patient goes to an emergency department that is in-network, he or she may still receive care from out-of-network providers working at that facility. *Id.* Second, a patient may schedule a medical procedure in advance at an in-network hospital or facility, but may not be aware that providers of ancillary services, such as radiologists, anesthesiologists, or pathologists, are out-of-network. *Id.* "Unlike most medical services, for which patients have an opportunity to seek in-network providers, patients generally are not able to choose these emergency and ancillary providers." Erin L. Duffy et al., *Policies to Address Surprise Billing Can Affect Health Insurance Premiums*, 26 AM. J. MANAGED CARE 401, 401 (2020) (AR 1384). The problem of surprise billing has been even more pronounced in a third circumstance, which arises when a patient receives services from an out-of-network air ambulance provider. *See* Erin C. Fuse Brown et al., *The Unfinished Business of Air Ambulance Bills*, HEALTH AFFAIRS FOREFRONT (Mar. 26, 2021) (AR 2843). These providers have imposed surprise bills on patients averaging tens of thousands of dollars. *Id.*

In such circumstances, the patient's inability to choose an in-network provider has created a distortion in the market wherein these providers have little incentive to join health plan or insurance networks, negotiate fair prices in advance for their services, or moderate their charges for out-of-network care. This market distortion has led to a widespread phenomenon of surprise billing. More than 20 percent of in-network emergency department visits involve care from out-of-network physicians. *See* Zack Cooper et al., *Out-of-Network Billing and Negotiated Payments for Hospital-Based Physicians*, 39 HEALTH AFFAIRS 24, 24 (Jan. 2020) (AR 3045). Similarly, elective surgeries, even at in-network facilities, result in an out-of-network bill from providers of ancillary services in more than 20

percent of cases. *See* Karan R. Chhabra et al., *Out-of-Network Bills for Privately Insured Patients Undergoing Elective Surgery with In-Network Primary Surgeons and Facilities*, 323 JAMA 538, 540 (2020) (AR 1408). And air ambulance services are even more likely to involve out-of-network care; in total, about 77 percent of air ambulance transports are performed by out-of-network providers. *See* Erin C. Fuse Brown et al., *Out-of-Network Air Ambulance Bills: Prevalence, Magnitude, and Policy Solutions*, 98 MILBANK QUARTERLY 747, 751 (2020) (AR 2855).

Before the enactment of the No Surprises Act, this out-of-network billing phenomenon had been rapidly growing, "becoming more common and potentially more costly in both the emergency department and inpatient settings." Eric C. Sun et al., *Assessment of Out-of-Network Billing for Privately Insured Patients Receiving Care in In-Network Hospitals*, 179 JAMA INTERN. MED. 1543, 1544 (2019) (AR 4580). From 2010 to 2016, "the incidence of out-of-network billing increased from 32.3% to 42.8% of emergency department visits, and the mean potential liability to patients increased from $220 to $628. For inpatient admissions, the incidence of out-of-network billing increased from 26.3% to 42.0%, and the mean potential liability to patients increased from $804 to $2040." *Id.* Air ambulance bills have "spiked over the past decade," with median charges for a fixed-wing transport "nearly tripling from $12,500 to $35,900 between 2008 and 2017." Erin C. Fuse Brown et al., *The Unfinished Business of Air Ambulance Bills*, HEALTH AFFAIRS FOREFRONT (Mar. 26, 2021) (AR 2845). Air Methods Corporation, in particular, took advantage of this market distortion by increasing its prices for medical transports by 283 percent from 2007 to 2016. Loren Adler et al., *High Air Ambulance Charges Concentrated in Private Equity-Owned Carriers*, USC-Brookings Schaeffer on Health Policy (Oct. 13, 2020) (AR 4769).

One factor leading to the recent explosion in out-of-network billing practices has been the increasing participation of private equity groups in the health care market through the acquisition of physician practices. This trend had been rapidly growing for years before the enactment of the No Surprises Act, with private equity deals relating to health care more than doubling between 2008 and 2018. *See Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980, 56,046 (Oct. 7, 2021) (AR 67) (citing Jane M. Zhu et al., *Private Equity Acquisitions of Physician Medical Groups Across Specialties, 2013-2016*, 323 JAMA 663, 663-665 (2020) (AR 1155-57)); *see also* Joseph D. Bruch et al., *Changes in Hospital*

Income, Use, and Quality Associated with Private Equity Acquisition, 180 JAMA INTERN. MED. 1428 (Aug. 24, 2020) (AR 1299). These investors have made a conscious business decision to forgo joining insurance networks in order to be able to charge higher prices out of network. *See* Zack Cooper et al., *Surprise! Out-Of-Network Billing for Emergency Care in the United States*, 128 J. POL. ECON. 3626, 3672-3673 (2020) (AR 3100-01). "Research on one large private equity-owned firm showed that when it entered a hospital network, out-of-network billing rates increased by more than 81 percentage points." H.R. REP. NO. 116-615, pt. I, at 54 (Dec. 2, 2020) (AR 331).

This has led to unexpected, and devastating, medical bills for patients. "[B]alance bills can be substantial. . . . [T]he mean potential balance bills for anesthesiologists, pathologists, radiologists, and assistant surgeons were $1,171, $177, $115, and $7,420, respectively." Cooper et al., 39 HEALTH AFFAIRS at 27; *see also* Erin L. Duffy et al., *Prevalence and Characteristics of Surprise Out-Of-Network Bills from Professionals in Ambulatory Surgery Centers*, 39 HEALTH AFFAIRS 783, 785 (2020) (AR 1391) (finding 81 percent increase in average amounts of surprise bills at ambulatory surgical centers from 2014 to 2017). "Given that nearly half of individuals in the US do not have the liquidity to pay an unexpected $400 expense without taking on debt, these out-of-network bills can be financially devastating to a large share of the population and should be a major policy concern." Cooper et al., 128 J. POL. ECON. at 3627 (AR 1067).

Even these average figures understate the devastating effect surprise bills have had on some patients. For example, patients have faced a $7,924 surprise bill after emergency jaw surgery; a $20,243 surprise bill for emergency care for a bike crash; and a $27,660 surprise bill after being hit by a public bus. Sarah Kliff, *Surprise Medical Bills, the High Cost of Emergency Department Care, and the Effects on Patients*, 2019 JAMA INTERN. MED. 1457, 1457 (2019) (AR 4013). "[A]mong the most shocking [examples of balance billing abuses] was a spinal surgery patient who received a bill of $101,000 despite having confirmed that her surgeon was in-network." H.R. REP. NO. 116-615, at 52 (AR 329).

Beyond the financial consequences in individual cases, the market distortion created by surprise billing has had the broader effect of driving up health care costs for all parties. This is because "the ability to bill out of network allows [emergency department] physicians to be paid in-network

rates that are significantly higher than those paid to other specialists who cannot readily bill out of network," and, as a result, "[t]hese higher payments get passed along to all consumers (including those who do not even access care) in the form of higher insurance premiums." Cooper et al., 39 HEALTH AFFAIRS at 24 (AR 1397). Emergency room physicians have been able to command higher in-network payment rates, a phenomenon "caused not by supply or demand, but rather by the ability to ambush the patient[.]" Cooper et al., 128 J. POL. ECON. at 3628 (AR 1068). Because emergency department care is so common, this practice "raise[s] overall health spending." *Id.* This has resulted in "commercial health insurance premiums as much as 5% higher than they otherwise would be in the absence of this market failure," Duffy et al., 26 AM. J. MANAGED CARE at 403 (AR 1385), placing a financial burden "on employer plan sponsors as well as individuals," *Examining Surprise Billing: Protecting Patients from Financial Pain: Hearing Before the H. Comm. on Educ. and Labor, Subcomm. on Health, Employment, Labor and Pensions*, 116th Cong. 39 (2019) (statement of Ilyse Schuman, Senior Vice-President, American Benefits Council) (AR 471).

II. Congress Enacted the No Surprises Act to Protect Patients from Surprise Billing Practices and to Control Health Care Costs.

Congress enacted the No Surprises Act to address these surprise billing practices and to rein in the cost of health care. Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, 134 Stat. 1182, 2758-2890 (2020). The Act protects insured patients from unexpected liabilities arising from the most common forms of balance billing. If an insured patient receives emergency care, or if he or she receives care that is scheduled at certain types of in-network facilities, health care providers and facilities are generally prohibited (absent, in certain circumstances, the patient's consent) from balance billing the patient for any part of his or her care that is furnished by an out-of-network provider or facility. *See* 42 U.S.C. §§ 300gg-131, 300gg-132, 300gg-135.[1] Likewise, the patient's cost-sharing

[1] The Act makes parallel amendments to the Public Health Service Act ("PHSA") (administered by the Department of Health and Human Services ("HHS")), the Employee Retirement Income Security Act ("ERISA") (administered by the Department of Labor), and the Internal Revenue Code (administered by the Department of the Treasury). In addition, the Act requires the Office of Personnel Management to ensure that that its contracts with Federal Employees Health Benefits Program carriers require compliance with applicable provisions in the same manner as group health

responsibilities for out-of-network services may not exceed his or her financial responsibilities "that would apply if such services were provided by a participating provider or a participating emergency facility[.]" 42 U.S.C. §§ 300gg-111(a)(1)(C)(ii), (b)(1)(A), 300gg-112(a)(1).[2] For example, if the patient's health insurance policy would require him or her to pay coinsurance of 20% of the cost of an in-network service, the patient's responsibility for any out-of-network service would be limited to the same 20% co-insurance. *Id.* § 300gg-111(a)(1)(C)(ii), (iii), (b)(1)(A), (B).

Crucially, to effectuate the statute's goal of "No Surprises," the patient's cost-sharing responsibilities are calculated "as if the total amount that would have been charged for such services by such participating provider or participating emergency facility were equal to the recognized amount." *Id.* § 300gg-111(a)(1)(C)(ii), (b)(1)(B). The "recognized amount" is a term of art under the statute. If an All-Payer Model Agreement is in place in a given State, or a specified State law applies with respect to a particular medical service, then the Agreement or the State law will determine the recognized amount.[3] Otherwise, the "recognized amount" is the "qualifying payment amount (as defined in subparagraph (E)) for such year and determined in accordance with rulemaking described in paragraph (2)(B)) for such item or service." *Id.* § 300gg-111(a)(3)(H)(ii); *see also id.* § 300gg-111(a)(2)(B) (directing the Departments to issue rules setting the methodology for determining the qualifying payment amount). With respect to air ambulance services, the patient's cost-sharing responsibilities are calculated on the basis of the rates that would apply for these services if they were furnished by such a participating provider, which the Departments interpret to be the lesser of the billed amount or the qualifying payment amount. *See* 42 U.S.C. § 300gg-112(a)(1); 86 Fed. Reg. at 36,884. Thus, in states without an All-Payer Model Agreement or applicable state law, the qualifying

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plans and health insurance issuers. 5 U.S.C. § 8902(p). For ease of reference, except where otherwise noted, this brief cites only to the Act's amendments to the PHSA.

[2] The provisions of the No Surprises Act that apply specifically to air ambulance services are codified in 42 U.S.C. § 300gg-112.

[3] Texas has enacted a State law that governs patient's cost-sharing responsibilities for out-of-network services and the arbitration process for disputes between providers and insurers over payments for such services. Tex. Ins. Code Ann. § 751.001 *et seq.* The State law does not apply to group health plans that are subject to ERISA. *See* 86 Fed. Reg. at 56,091.

payment amount determines the patient's financial obligations at the outset. The qualifying payment amount serves an essential role to provide clarity and predictability to patients to protect them from surprise medical bills.

The "qualifying payment amount," in turn, is also a statutory term of art. It is generally defined, for a given item or service and for a given plan or insurer, as "the median of the contracted rates recognized" by the group health plan or insurer, measured with respect to the payment rates for "the same or a similar item or service that is provided by a provider in the same or similar specialty and provided in the geographic region in which the item or service is furnished," under all the plans offered by that insurer in a given insurance market. 42 U.S.C. §§ 300gg-111(a)(3)(E)(i)(I), 300gg-112(c)(2). The qualifying payment amount is based on the insurer's or group health plan's calculation of the median contracted rates for its plans as of January 31, 2019; this amount is subject to an inflation adjustment under a methodology to be established by the Departments. *Id.* § 300gg-111(a)(3)(E)(i)(I). The statute thus textually treats the "qualifying payment amount," calculated in this manner, as a reasonable proxy for what the in-network payment rate would have been for a given out-of-network service, for the purposes of calculating an insured patient's cost-sharing responsibilities.

In addition to setting the rules to determine a patient's payment obligations for a particular out-of-network medical service, the Act also establishes a procedure to resolve disputes between health care providers or facilities and plans or insurers over the amount of payment for such a service, in which the "qualifying payment amount" is again used as a reference point. The Act specifies that a plan or insurer will issue an initial payment, or notice of a denial of payment, to a provider or facility within 30 calendar days after the provider or facility submits a bill to the plan or insurer for an out-of-network service. *Id.* §§ 300gg-111(a)(1)(C)(iv), (b)(1)(C), 300gg-112(a)(3)(A). If the provider or facility is not satisfied with this determination, it may initiate a 30-day period of open negotiation with the plan or insurer over the claim. *Id.* §§ 300gg-111(c)(1)(A), 300gg- 112(b)(1)(A). If those negotiations do not resolve the dispute, the parties may then proceed to an independent dispute resolution process. *Id.* §§ 300gg-111(c)(1)(B), 300gg-112(b)(1)(B). The statute provides for an independent dispute

resolution process that furthers Congress's goals of "encouraging the efficiency . . . and minimiz[ing] costs[.]" *id.* 300gg-111(c)(3)(A).

The Act specifies that the Departments "shall establish by regulation," no later than December 27, 2021, "one independent dispute resolution process . . . under which[]" an arbitrator, known in the statute as a "certified IDR entity," "determines, . . . in accordance with the succeeding provisions of this subsection, the amount of payment under the plan or coverage for such item or service furnished by such provider or facility." *Id.* §§ 300gg-111(c)(2)(A), 300gg-112(b)(2)(A). The Act further instructs the Departments to "establish a process" to certify arbitrators, *id.* § 300gg-111(c)(4)(A), under which such an entity "meets such other requirements as determined appropriate by the Secretary," *id.* §§ 300gg-111(c)(4)(A)(vii), 300gg-112(b)(4)(A). The Departments are also instructed to "provide for a method" under which the parties to a dispute either jointly select an arbitrator or defer to the Departments' selection. *Id.* §§ 300gg-111(c)(4)(F), 300gg-112(b)(4)(B).

The Act establishes a system of "baseball" arbitration under which both the provider or facility and the group health plan or insurer will each submit a proposed payment amount, with an explanation, and the arbitrator will select one or the other offer as the amount of payment for the item or service that is in dispute, "taking into account the considerations specified in subparagraph (C)." *Id.* §§ 300gg-111(c)(5)(A)(i), 300gg-112(b)(5)(A)(i). Although Congress considered versions of bills that left the payment determination to the unbridled discretion of the arbitrator, *see, e.g.*, S. 1266, 116th Cong. (2019); H.R. 4223, 116th Cong. (2019), as well as versions of the bill that would have adopted the qualifying payment amount as the default payment amount, *see, e.g.*, H.R. 3630, 116th Cong. (2019); S. 1895, 116th Cong. (2019), it ultimately settled on a compromise that provided statutory parameters that instruct arbitrators to consider the qualifying payment amount alongside other relevant information.

Subparagraph (C) begins by instructing the arbitrator to consider "the qualifying payment amounts (as defined in subsection (a)(3)(E)) for the applicable year for items or services that are comparable to the qualified IDR item or service and that are furnished in the same geographic region (as defined by the Secretary for purposes of such subsection) as such qualified IDR item or service."

42 U.S.C. §§ 300gg-111(c)(5)(C)(i)(I), 300gg-112(b)(5)(C)(i)(I). Subparagraph (C) then goes on to set forth several examples of "additional information" and "additional circumstances" for the arbitrator to consider. *Id.* §§ 300gg-111(c)(5)(C)(i)(II), (C)(ii), 300gg-112(b)(5)(C)(i)(II), (C)(ii). The "additional circumstances" for non-air ambulance providers include: the provider's level of training, experience, and quality and outcomes measurements; the market share of the provider, facility, plan, or insurer; the acuity of the individual receiving the medical service, or the complexity of that service; the provider's teaching status, case mix, and scope of services; and a demonstration of the provider's or the plan's or insurer's good faith efforts to enter into network agreements for the service, or the lack of such efforts. *Id.* § 300gg-112(b)(5)(C)(i)(II), (C)(ii). The "additional circumstances" for air ambulance services include: the quality and outcome measurements of the air ambulance service provider; the acuity of the individual receiving the service or the complexity of furnishing the service to the individual; the training, experience, and quality of the medical personnel that furnished the service; the type of ambulance vehicle; the population density of the patient's pick up location; and a demonstration of the provider's or the plan's or insurer's good faith efforts to enter into network agreements for the service, or the lack of such efforts. *Id.* § 300gg-112(b)(5)(C)(ii).

The "additional information" for the arbitrator to consider includes any "information as requested by the certified IDR entity relating to such offer[,]" and "any information relating to such offer submitted by either party[.]" *Id.* §§ 300gg-111(c)(5)(B)(i)(II), (B)(ii), 300gg-112(b)(5)(B)(i)(II), (B)(ii). The arbitrator is prohibited from considering the provider's usual and customary charges for an item or service, the amount that the provider would have billed for the item or service in the absence of the Act, or the reimbursement rates for the item or service under the Medicare or Medicaid programs. *Id.* §§ 300gg-111(c)(5)(D), 300gg-112(b)(5)(C)(iii). The arbitrator's decision is binding on the parties and is not subject to judicial review except under certain circumstances described in the Federal Arbitration Act. *Id.* §§ 300gg-111(c)(5)(E), 300gg-112(b)(5)(D).

The Act requires the Departments to publish a report for each calendar quarter that states, among other things, "the number of times the payment amount determined (or agreed to) under this subsection exceeds the qualifying payment amount, specified by items and services[,]" and for each

dispute decided by an arbitrator, "the amount of such offer so selected expressed as a percentage of the qualifying payment amount." *Id.* §§ 300gg-111(c)(7)(A)(v), (B)(iv), 300gg-112(b)(7)(A)(iv), (B)(iv). The arbitrator shall submit such information to the Departments as they determine necessary to enable them to carry out these publication requirements. *Id.* §§ 300gg-111(c)(7)(C), 300gg-112(b)(7)(C).

Congress thus selected an approach to the resolution of provider-insurer payment disputes that was "designed to reduce premiums and the deficit." H.R. REP. NO. 116-615, at 58 (AR 335); *see also id.* at 48 (AR 325) (structuring the IDR process "to reduce costs for patients and prevent inflationary effects on health care costs"). The Act would not succeed in this goal, however, if arbitrations are lengthy, drawn-out proceedings or result routinely in payments greater than median in-network payment amounts; such a process would *increase* both federal deficits and health insurance premiums. *See id.* at 57. The Congressional Budget Office ("CBO") scored the Act on the understanding that Congress had avoided this pitfall, finding that the Act's arbitration procedures will result in "smaller payments to some providers [that] would reduce premiums by between 0.5 percent and 1 percent. Lower costs for health insurance would reduce federal deficits because the federal government subsidizes most private insurance through tax preferences for employment-based coverage and through the health insurance marketplaces established under the Affordable Care Act." CBO, *Estimate for Divisions O Through FF H.R. 133, Consolidated Appropriations Act, 2021, Public Law 116-260 Enacted on December 27, 2020* at 3 (Jan. 14, 2021) (AR 781).[4] In total, the Act is expected to reduce the deficit by $16.8 billion, over ten years. *Id.* at 7 (AR 785).

III. The Departments Issued Rules to Implement the Act's Framework to Protect Patients and to Control Health Care Costs.

As noted above, Congress instructed the Departments to issue one set of rules no later than July 1, 2021, addressing the No Surprises Act's patient protections, and to issue a second set of rules

[4] *See also* CBO, *H.R. 5826, the Consumer Protections Against Surprise Medical Bills Act of 2020, as Introduced on February 10, 2020: Estimated Budgetary Effects* at 1 (Feb. 11, 2020) (AR 1757) ("[Under] H.R. 5826 . . . , dispute resolution entities would be instructed to look to the health plan's median payment rate for in-network rate care. . . . [U]nder the bill, . . . average payment rates for both in- and out-of-network care would move toward the median in-network rate, which tends to be lower than average rates. CBO and JCT estimate that in most affected markets in most years, lower payments to some providers would reduce premiums by between 0.5 percent and 1 percent," also lowering federal deficits).

no later than December 27, 2021, addressing the procedures for resolving payment disputes. 42 U.S.C. §§ 300gg-111(a)(2)(B), (c)(2)(A), 300gg-112(b)(2)(A).

The Departments released their first set of interim final rules in July 2021. *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872 (July 13, 2021). Those rules implemented the Act's provisions that prohibit providers and facilities from balance billing their patients for out-of-network medical services in certain situations; limit patients' cost-sharing responsibilities for these services; require providers to make disclosures to patients of federal and state protections against balance billing; codify certain additional patient protections; and set forth complaint processes with respect to violations of the Act's balance billing and out-of-network cost sharing protections. *See id.* at 36,876. The July interim final rules also set the methodology for determining the qualifying payment amount. *See id.* Those rules are not challenged here. *See* Complaint at 33, *LifeNet Inc., v. HHS*, 6:22-cv-00373 (E.D. Tex.), ECF. No. 1; Complaint at 21, 24, *Tex. Med. Ass'n. et al., v. HHS*, 6:22-cv-00372 (E.D. Tex.), ECF No. 1.

The Departments released a second set of interim final rules in September 2021. *Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021). These interim final rules implemented the Act's provisions requiring health care providers to furnish good-faith estimates of the cost of medical services to uninsured individuals; establishing a procedure for these individuals to dispute bills that exceed these good-faith estimates; extending the Affordable Care Act's external review requirements to adverse benefit determinations under the Act's surprise billing provisions; and clarifying that carriers under the Federal Employees Health Benefits Program generally are subject to the Act's terms. *See id.* at 55,984-87. This rule set forth procedures for arbitrators to be certified, and for providers, facilities, group health plans, and insurers to invoke the Act's independent dispute resolution system. *See id.* at 55,985.

The September interim final rule also addressed the factors that the arbitrator should consider in deciding between the competing offers to be submitted by providers, facilities, plans and insurers setting the out-of-network payment amount for a given medical service. Under the September interim final rule, the arbitrator was required to "select the offer closest to the qualifying payment amount

unless [it] determines that credible information submitted by either party . . . clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions." *Id.* at 56,104.

In October 2021, the Texas Medical Association ("TMA") and Dr. Adam Corley filed a lawsuit against the Departments asserting that the provisions of the September interim final rules relating to the certified IDR entities' consideration of the qualifying payment amount in deciding which offer to select should be vacated. *TMA I*, 587 F. Supp. 3d at 536. In February 2022, this Court vacated those portions of the September interim final rule. *Id.* at 549. In April 2022, LifeNet, Inc., a provider of air ambulance services, filed a lawsuit against the Departments seeking vacatur of parallel provisions of the September interim final rule specific to arbitrations for air ambulance services. *LifeNet I*, 2022 WL 2959715, at *1. In July 2022, this Court vacated those provisions of the interim final rule. *Id.* at *10.

IV. The August Final Rule

The Departments received thousands of comments on various aspects of the interim final rules. After considering those comments, in August 2022, the Departments issued a final rule relating to the certified IDR entity's payment determination under the Federal IDR process.[5]

The final rule provides instruction for making payment determinations in the IDR process to replace the provisions vacated by this Court in *TMA I* and *LifeNet I*. Notably, the August 2022 final rule does not require the certified IDR entity to select the offer closest to the qualifying payment amount, as the Departments repeatedly explained. *Eg.*, *Requirements Related to Surprise Billing*, 87 Fed. Reg. 52,618, 52,627 (Aug. 26, 2022) ("The Departments note that these final rules are not intended to impose a rebuttable presumption [in favor of the qualifying payment amount]. . . . The regulatory text in these final rules does not include the provisions that the District Court reasoned would have the effect of imposing such a presumption."). Instead, the final rule specifies that "[t]he certified IDR

[5] The August 2022 final rule also imposes additional disclosure requirements on insurance plans or issuers in instances where the billing code has been "downcoded" by the insurers. Those provisions of the August 2022 final rule are not challenged here.

entity must select the offer that the certified IDR entity determines best represents the value of the qualified IDR item or service." 45 C.F.R. § 149.510(c)(4)((ii)(A).[6] The final rule explains that, in making that selection, the certified IDR entity must consider all permissible information submitted by the parties and "should evaluate whether the information is credible and relates to the offer submitted by either party for the payment amount for the qualified IDR item or service that is the subject of the payment determination. The certified IDR entity should not give weight to information to the extent it is not credible, it does not relate to either party's offer for the payment amount for the qualified IDR item or service, or it is already accounted for by the qualifying payment amount . . . or other credible information." 45 C.F.R. §§ 149.510(c)(4)(iii)(E), 149.520(b)(3).[7]

V. This Case

The Plaintiffs in the lead consolidated case, TMA, Dr. Adam Corley, and Tyler Regional Hospital, LLC, bring this suit to challenge the provisions of the final rule that instruct the arbitrator not to give weight to information that is not credible, does not relate to either party's offer, or is already accounted for in other information submitted to the arbitrator in non-air ambulance arbitrations.

LifeNet, Inc., challenges parallel provisions of the final rule that apply to air ambulance services. LifeNet provides air ambulance services in Texas, Arkansas, Oklahoma, and Louisiana. It is paid for its services by Air Methods Corporation, a national air ambulance company that contracts with local partners. *See* LifeNet Mot. for Summ. J. and Mem. in Supp. ("LifeNet MSJ Mem."), *Tex. Med. Ass'n v. HHS*, No. 6:22-cv-372, ECF No. 42 (E.D. Tex. Oct. 12, 2022); *see also id.* LifeNet MSJ Mem., Ex. G, Declaration of James L. Gaines ¶ 5, ECF No. 42-3 ("Gaines Decl."). The contract "sets an agreed amount of compensation for LifeNet's emergency air transport services, which amount is to be paid to LifeNet by Air Methods." Pl.'s Mot. for Summ. J. and Mem. in Supp. 11, *LifeNet, Inc. v. HHS et al.*, No. 6:22-cv-162, ECF No. 27 (E.D. Tex. May 18, 2022). "According to the contract, Air Methods is responsible for

[6] The final rule sets forth parallel regulations implemented by HHS, the Department of Labor, and the Department of the Treasury. For ease of reference, except where otherwise noted, this brief cites only to the HHS regulations.

[7] The regulation addressing payment disputes involving out-of-network air ambulance services, 45 C.F.R. § 149.520(b)(1), incorporates "the requirements of § 149.510."

collecting reimbursement from other payors (e.g., patients, health plans, health insurers) for LifeNet's services." *Id.* "But Air Methods owes the agreed amount to LifeNet, for a given transport, even if Air Methods is unsuccessful at collecting reimbursement for that transport from other payors." *Id.*

STANDARD OF REVIEW

"As the party invoking federal jurisdiction, the plaintiffs bear the burden of demonstrating that they have standing." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2207 (2021). That burden "becomes gradually stricter as the parties proceed through the successive stages of the litigation." *In re Deepwater Horizon*, 739 F.3d 790, 799 (5th Cir. 2014) (quoting *Lewis v. Casey*, 518 U.S. 343, 358 (1996)). "[A]t the summary judgment stage, such a party can no longer rest on mere allegations, but must set forth specific facts that adequately support their contention." *California v. Texas*, 141 S. Ct. 2104, 2117 (2021).

When evaluating a challenge to an agency's interpretation of a statute, a court should first ask "whether Congress has directly spoken to the precise question at issue." *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984). If it has, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842-43. Where Congress has not spoken directly to the issue at hand, the court should defer to the agency's interpretation so long as it is "based on a permissible construction of the statute." *Id.* at 843. That is true "even if the agency's reading differs from what the court believes is the best statutory interpretation." *Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 980 (2005).

When reviewing agency action under the Administrative Procedure Act ("APA"), a court may set aside agency action when it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *United States v. Johnson*, 632 F.3d 912, 928 (5th Cir. 2011) (quoting 5 U.S.C. § 706(2)(A)). This standard is "narrow and highly deferential." *Sierra Club v. U.S. Dep't of Interior*, 990 F.3d 909, 913 (5th Cir. 2021). "[T]he court is not to substitute its judgment for that of the agency." *Id.* Rather, the court "consider[s] whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Id.* (citation omitted). In short, the

arbitrary-and-capricious standard simply "requires that agency action be reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021).

ARGUMENT

I. Plaintiffs Have Not Shown That They Have Standing to Challenge the Final Rule's Arbitration Procedures.

To establish Article III standing, Plaintiffs must show that they have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016); *see also Ortiz v. Am. Airlines, Inc.*, 5 F.4th 622, 628 (5th Cir. 2021). To establish an injury in fact, Plaintiffs must show they have suffered "an invasion of a legally protected interest [that] is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Kitty Hawk Aircargo, Inc v. Chao*, 418 F.3d 453, 458 (5th Cir. 2005) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)). None of the Plaintiffs have met that standard here. The final rule disclaims the presumption concerning the qualifying payment amount that this Court previously found to give Plaintiffs standing—as the Departments specifically and repeatedly explained—and Plaintiffs offer nothing but speculation to suggest that the provisions they challenge actually affect which offer an arbitrator would ultimately select and injure them in any way.

A. Plaintiffs Have Not Shown They Are Likely to Suffer an Injury in Fact Fairly Traceable to the Challenged Provisions of the Final Rule.

Plaintiffs have not adequately shown that they have standing to challenge the final rule. Indeed, the TMA Plaintiffs make no effort to show standing at all, instead simply referencing this Court's conclusion in *TMA I* that the Plaintiffs had standing to challenge the interim final rule. Pls.' Mot. for Summ. J. and Mem. in Supp. ("TMA MSJ Mem.") 9 n.6, *Texas Med. Ass'n v. HHS et al.*, No. 6:22-cv-372, ECF No. 41 (E.D. Tex. Oct 12, 2022). But the final rule differs in material respects from its predecessor, so regardless of whether Plaintiffs had standing to challenge the interim final rule, *see*

Cross-Mot. For Summ. J. 16-18, *Tex. Med. Ass'n v. HHS*, No. 6:21-cv-425, ECF No. 62 (E.D. Tex. Jan. 10, 2022), it is their burden to show how the portions of the final rule challenged in this lawsuit injure them. And, unlike in the previous lawsuit, here Plaintiffs do not challenge the portion of the final rule that determines which offer the arbitrator will actually select—instead they challenge ancillary evidentiary rules that will cause them no harm.

The core deficiency in Plaintiffs' case is that the final rule does not actually do what Plaintiffs claim it does. To the extent Plaintiffs claimed a likelihood of injury based on the presumption in favor of the qualifying payment amount in the first round of litigation, those complaints have been addressed by the Departments in promulgating the final rule, which lacks such a presumption. *See, e.g.*, 87 Fed. Reg. at 52,627 ("The Departments note that these final rules are not intended to impose a rebuttable presumption. . . . The regulatory text in these final rules does not include the provisions that the District Court reasoned would have the effect of imposing such a presumption."). Plaintiffs' theory of injury thus rests on the erroneous premise that the final rule reimposes a presumption in favor of the qualifying payment amount—but nowhere in the text of the final rule, or the preamble, is the arbitrator instructed to defer to the qualifying payment amount. *Id.* at 52,627-28 ("The Departments note that these final rules do not require certified IDR entities to default to the offer closest to the qualifying payment amount or to apply a presumption in favor of that offer."). Plaintiffs' attempts to manufacture injury by advancing an idiosyncratic, a-textual interpretation of the final rule are insufficient, at this stage, to establish the facts needed to support standing. *See California*, 141 S. Ct. at 2117 (proof, such as "specific facts" in affidavits, is necessary to support a claim of standing at summary judgment); *see also Ortiz*, 5 F.4th at 628. Plaintiffs offer nothing more than speculation that any arbitrator would understand challenged provisions to create a presumption in favor of the qualifying payment amount—particularly given the Departments' explicit and repeated clarifications that the final rule does no such thing. *See* 87 Fed. Reg. at 52,627-28.

Missouri v. Yellen, 39 F.4th 1063 (8th Cir. 2022), *petition for cert. filed*, No. 22-352 (Oct 14, 2022) is instructive. There, the Eighth Circuit held that Missouri lacked standing to challenge provisions of an interim final rule where "Missouri's complaint and appeal make clear . . . that the State is not challenging the Offset Restriction as written, but rather a specific potential interpretation of the provision—the 'broad interpretation.'" *Id.* at 1069. Missouri's standing argument failed, that court found, because "there is no threatened application of the broad interpretation. The Secretary explained to the district court and to this court, and Treasury reiterated in the Interim and Final Rules, that the Secretary has never endorsed or adopted the broad interpretation." *Id.* So too, here, the Departments have explained that the final rule does not impose a presumption in favor of the qualifying payment amount. *See* 87 Fed. Reg. at 52,627-28. Plaintiffs' attempt to manufacture standing thus fails.

Fundamentally, Plaintiffs lack standing because they have not demonstrated that they are likely to suffer an injury in fact as a result of the challenged provisions of the final rule. Rather, the briefing reveals only speculation about the possibility that they will be disadvantaged in future arbitrations in a way that will injure them and be traceable to the final rule. Notably, Plaintiffs hypothesize about how the final rule will impact the actions of plans and insurers. *See, e.g.*, TMA MSJ Mem., Ex. A, Declaration of Dr. Christopher Ryan Cook ¶ 9, ECF No. 41-1 ("Cook Decl.") ("[I]nsurers have just pushed down their reimbursement offers to the relevant [qualifying payment amount]."); TMA MSJ Mem., Ex. B, Declaration of Dr. Adam Corley ¶ 15, ECF No. 41-2 ("Corley Decl.") ("Because the Final Rule privileges the [qualifying payment amount] during the IDR process, it incentivizes insurers to offer nothing more than the [qualifying payment amount] during Open Negotiation[.]"). These statements do not bear on whether the *arbitrator* might be more likely to select the insurer's offer over the provider's offer, since Plaintiffs' speculation about what *insurers* will do does not affect what an *arbitrator* will do. Plaintiffs' burden cannot be satisfied by a conclusory statement or wild speculation. *Kitty Hawk Aircargo*, 418 F.3d at 459.

Additionally, Plaintiffs challenge the portions of the final rule that instruct arbitrators not to give weight to information that is not credible or not relevant to the arbitrator's task of selecting an offer of payment. But Plaintiffs do not argue that they intend to submit noncredible or irrelevant information to the arbitrators, or that they will be harmed by the arbitrators' failure to give that information weight. *See* TMA MSJ Mem. 22 ("surely arbitrators will not give weight to information they deem noncredible"). Thus, again, they offer nothing more than speculation that challenged portions of the final rule that provide procedural and methodological instruction to arbitrators will have any impact on which offer the arbitrator ultimately selects.[8]

B. LifeNet has Failed to Demonstrate Standing.

LifeNet also lacks standing for additional reasons (beyond the ones discussed above which apply to all Plaintiffs). LifeNet has "resubmit[ed], here, substantially the same evidence that [it] submitted in its previous action" to support standing. LifeNet MSJ Mem. 8. Although Defendants recognize that this Court previously rejected their argument that LifeNet lacked standing to challenge the interim final rule, Defs.' Cross-Mot. for Summ. J., 14-17, *LifeNet, Inc. v. HHS et al.*, No. 22-cv-162, ECF No. 31 (E.D. Tex. June 1, 2022); *LifeNet I*, 2022 WL 2959715, at *6-8, Defendants respectfully maintain that the same arguments apply to the final rule, and that LifeNet has failed to meet its burden on standing.

[8] In any event, recent data has only undermined Plaintiffs' speculation. It is unclear what impact, if any, detailed regulations have on arbitrators. A recent study assessing Texas IDR payment outcomes for clinicians and comparing them with arbitration benchmarks found that "arbiters may anchor to a median in-network price benchmark, even if they are not instructed on how to weigh various factors." Erin Duffy et al., *Research Letter: Dispute Resolution Outcomes for Surprise Bills in Texas*, 327 JAMA, 2350, 2351 (2022) (AR 11803). That is, the study casts serious doubt on whether the particular rules instructing arbitrators in surprise billing arbitrations actually affects the behavior of arbitrators. *Id.* Plaintiffs' complaint, then, seems to be with the statute that requires arbitrators to consider the qualifying payment amount as one of the factors in their deliberations, rather than with any particular rule that gives guidance to the arbitrators on how to compare the various factors.

Principally, LifeNet is not an object of the regulation, nor will the challenged regulation cause financial harm to LifeNet. After all, LifeNet is paid for its services by Air Methods Corporation, a national air ambulance company that contracts with local partners. Gaines Decl. ¶ 5; *see supra* 16. Only Air Methods has a financial interest in the outcome of those arbitrations; Plaintiff is paid a fixed amount *regardless* of the amount that Air Methods is reimbursed by an insurer or plan. *See supra* 16. To that end, LifeNet is not the object of the final rule—and it suffers no injury-in-fact from the operation of the final rule. *See Kitty Hawk Aircargo*, 418 F.3d at 459. LifeNet has also failed to prove causation and redressability. LifeNet's compensation is determined by its contract with Air Methods—and not by the arbitrator or by the Departments. There is no "likelihood that the requested relief will redress the alleged injury" by motivating Air Methods to provide higher fees for LifeNet's services. *Ark. Proj. v. Shaw*, 775 F.3d 641, 648 (5th Cir. 2014) (quoting *In re Stewart*, 647 F.3d 553, 557 (5th Cir. 2011). And LifeNet's contention that possible lower payment determinations by arbitrators will in turn "inevitably harm LifeNet directly whenever its current contract with AirMethod ends" is not a sufficiently concrete economic harm to support standing. LifeNet MSJ Mem. 14.

Nor is there any cognizable procedural injury to LifeNet. A "deprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing." *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009). LifeNet simply states that the final rule "'deprives' LifeNet 'of the arbitration process established by the Act.'" LifeNet MSJ Mem. 12 (quoting *LifeNet I*, 2022 WL 2959715, at *7). But it is not clear how LifeNet would suffer any concrete injury from the regulation, as its compensation is not affected by the outcome of the arbitrations: LifeNet's payment rates are guaranteed by contract.

Last, there is no reputational harm to LifeNet as a result of the final rule, much less any harm sufficient to make out the basis for standing. LifeNet argues that if it ever "seeks to borrow money or makes capital investments" its potential valuation will be lower because, it speculates, "the results of

today's IDRs will be significantly lower . . . , [and therefore] today's results will harm LifeNet." *Id.* at 14, 15. But LifeNet does not allege that it has any present plans to borrow money or make capital investments. On its face, that argument, too, relies on sheer speculation.

II. The Departments had the Authority and the Obligation to Issue Rules Establishing Procedures and Guidance for IDR Proceedings.

A. The Departments Properly Exercised their Rulemaking Authority in Promulgating the Final Rule and are Therefore Entitled to Deference.

The Departments issued the August final rule to fulfill Congress's instructions that they "*shall* establish by regulation one independent dispute resolution process . . . under which . . . [the arbitrator] determines, subject to subparagraph (B) and in accordance with the succeeding provisions of this subsection, the amount of payment under the plan or coverage for such item or service furnished by such provider or facility." 42 U.S.C. § 300gg-111(c)(2)(A) (emphasis added). Plaintiffs contend the Act leaves no room for the Departments to exercise their rulemaking authority. TMA MSJ Mem. 16. But not only may the Departments establish the process to determine payment amounts in IDR arbitrations, they *must* do so. The No Surprises Act expressly provides for the Departments to promulgate rules to govern the arbitrators' determination of the out-of-network payment rate for items and services through the IDR process. The Departments' exercise of this rulemaking authority is thus entitled to deference under *Chevron*. And the rule easily survives under this deferential standard. At the very least, this is a permissible reading of the statute, and the Departments reasonably resolved any statutory doubt in favor of a reading that furthers the statute's goal of lowering health care costs by creating a consistent and efficient process for resolving payment disputes.

The only constraint Congress imposed on the Departments is that the regulations be "in accordance with" the succeeding provisions of subsection (c). 42 U.S.C. § 300gg-111(c)(2)(A). The unstated premise of Plaintiffs' argument is that "in accordance with" restricts agencies to merely parroting the statutory language and nothing more. But that is not what "in accordance with" means,

or at the very least, that is not the only reasonable interpretation of that phrase. *See, e.g.*, *Sweeney v. Westvaco Co.*, 926 F.2d 29, 35 (1st Cir. 1991) (Breyer, J.) (explaining that "in accordance with" is ambiguous and could mean "mandated" by or "not forbid[den]" by); *see also United States v. Curb*, No. 06 CR 324-31, 2019 WL 2017184, at *4 (N.D. Ill. May 7, 2019) ("To be 'in accordance' does not require precise equivalency, but only agreement, conformity, or consistency."). Here, the instruction that the Departments promulgate rules "in accordance with" the general statutory factors described in (c)(5) is most naturally read with the "not inconsistent with" or "not forbidden by" interpretation of that phrase. If agencies were limited to parroting the statute, there would be no reason for Congress to grant them rulemaking authority. Congress should not be presumed to make empty gestures. *See Fund for Animals, Inc., v. Kempthorne*, 472 F.3d 872, 878 (D.C. Cir. 2006) (Kavanaugh, J.) ("[T]hat plaintiffs interpret [certain statutory provisions] to be an empty gesture is yet another indication that their submission is erroneous.").

This reading is consistent with the well-settled principle that agencies have authority to promulgate evidentiary rules governing adjudications under their purview. *See Nat'l Min. Ass'n v. Dep't of Labor*, 292 F.3d 849, 868 (D.C. Cir. 2002) (per curiam) (explaining that courts "give particular deference to an agency's promulgation of evidentiary rules governing its own adjudications; the agency's defense of those regulations need only be 'reasonable' so long as they are not 'inconsistent with a federal statute'") (quoting *Chem. Mfrs. Ass'n v. Dep't of Transp.*, 105 F.3d 702, 706 (D.C. Cir. 1997)). Thus, because there was a gap to fill in the Act regarding processes and procedures for determining out-of-network payment amounts, the job of filling that gap belongs to the Departments that are charged with administering the Act. *See New York v. Reilly*, 969 F.2d 1147, 1150 (D.C. Cir. 1992) (deferring to EPA's analysis of Clean Air Act factors); *Cent. Vt. Ry., Inc. v. Interstate Commerce Comm'n*, 711 F.2d 331, 336 (D.C. Cir. 1983) (deference to an *agency's* treatment of a set of statutory factors in adjudications). In this regard, Plaintiffs' reliance on *Ramirez v. U.S. Immigration and Customs*

Enforcement, 471 F. Supp. 3d 88, 176 (D.D.C. 2020), is misplaced. In that case, the court explained that, where Congress does not provide a structure or guidance for consideration of a variety of factors, it is up to the agency, not each individual adjudicator, to set rules for the consideration of those factors. *Id.*

Plaintiffs' contention that the Departments have no rulemaking authority at all over the arbitration process is fundamentally mistaken. TMA MSJ Mem. 16-17. Congress has specifically delegated to the Departments the authority to "establish by *regulation*" the arbitration process to determine out-of-network payment amounts. 42 U.S.C. § 300gg-111(c)(2)(A) (emphasis added). Even if the Act is unambiguous in not elevating the qualifying payment amount above the other statutory factors, there remain, contrary to Plaintiffs' interpretation, many other gaps and ambiguities in the IDR proceedings, gaps and ambiguities which the Department may fill through rulemaking. *Nat'l Cable & Telecomm. Ass'n*, 545 U.S. at 986 (under *Chevron* a court first asks "whether the statute's plain terms 'directly addres[s] the *precise* question at issue.'") (quoting *Chevron,* 467 U.S. at 843) (emphasis added). The Act, for example, is silent on how the arbitrators should weigh information presented to them, and what guiding principles or methodologies arbitrators should use in deciding which offer to select. And the very point of *Chevron* is that, where Congress has delegated authority to an agency to administer a statute (as it has explicitly done here), "[s]tatutory ambiguities will be resolved, within the bounds of reasonable interpretation, not by the courts but by the administering agency." *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013). Under *Chevron*, this delegation of authority empowers the Departments to resolve ambiguities as to which arbitration rules would be "in accordance with the succeeding provisions of [that] subsection," including that subsection's discussion of the considerations for the arbitrator to take into account in setting an out-of-network payment amount. 42 U.S.C. § 300gg-111(c)(2)(A).

Plaintiffs note that the Act includes additional grants of rulemaking power over specific matters such as the certification of arbitrators, and they invoke the *expressio unius* canon to argue that this means Congress must have denied the Departments rulemaking power over any other aspects of the arbitration process. TMA MSJ Mem. 17 & n.8. But that canon is of "limited usefulness . . . in the administrative context," *Tex. Office of Pub. Util. Counsel v. FCC*, 183 F.3d 393, 443 (5th Cir. 1999), particularly given that Congress often grants agencies overlapping sets of regulatory authorities to "make assurance double sure," *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 697 (D.C. Cir. 2014); *see also id.* at 698 (noting that *expressio unius* is a "feeble helper in an administrative setting"). Congress gave the Departments rulemaking authority over the arbitration process, and deference is thus owed to the Departments' interpretation of the statute in exercising that authority. *See City of Arlington*, 569 U.S. at 296-97.

Presumably in recognition of this legal principle, TMA participated robustly in the administrative rulemaking process throughout 2021, and repeatedly invited the Departments to exercise their substantive rulemaking authority to set rules governing how arbitrators would consider the Act's statutory factors. *See, e.g.,* Letter from E. Linda Villarreal, President, Tex. Med. Ass'n, et al., to Xavier Becerra, Secretary, U.S. Dep't of Health & Human Servs., et al., at 16 (Sept. 7, 2021) (AR 7832) (urging the Departments "to require the IDR entity . . . *not* to weigh the [qualifying payment amount] more than any other submitted information when picking a party's offer."). TMA's acknowledgment of the Departments' rulemaking authority in their comments precludes them from "revers[ing] course" now to deny that authority here. *S. Coast Air Quality Mgmt. Dist. v. EPA*, 472 F.3d 882, 892 (D.C. Cir. 2006).

III. The Departments Used Their Regulatory Authority to Reasonably Instruct Arbitrators to Apply Consistent Methodology in Selecting the Offer that Best Represents the Value of the Qualified IDR Item or Service.

A. The Final Rule Does Not Create a Presumption in Favor of the Qualifying Payment Amount but Rather Imposes Reasonable Evidentiary and Procedural Rules.

The final rule does not re-establish the "presumption" in favor of the qualifying payment amount vacated by this Court in *TMA I* and *LifeNet I*, as the Departments took pains to explain *See* 87 Fed. Reg. at 52,627 ("The regulatory text in these final rules does not include the provisions that the District Court reasoned would have the effect of imposing such a presumption."); *id.* at 52,628 ("these final rules do not require certified IDR entities to default to the offer closest to the [qualifying payment amount] or to apply a presumption in favor of that offer").

To the contrary, the final rule instructs arbitrators to "select the offer that the certified IDR entity determines best represents the value of the qualified IDR item or service." 45 C.F.R. § 149.510(c)(4)(ii)(A). Plaintiffs do not challenge this part of the final rule, and indeed appear to take no issue with the portion of the rule that actually instructs arbitrators which offer to select. Instead, they paint a straw man, challenging a smattering of other provisions that they say, taken together, amount to a presumption in favor of the qualifying payment amount. But the final rule does no such thing. None of the challenged portions of the final rule change the fact that the arbitrator is tasked with selecting the offer that best represents the value of the item or service, regardless of whether that offer happens to be closest to the qualifying payment amount.

Plaintiffs train their fire on ancillary provisions of the final rule that are intended to provide instruction to arbitrators in how to approach making payment determinations "to ensure that certified IDR entities have clear guidance on how to evaluate potentially voluminous and complex information in a methodological and consistent manner." 87 Fed. Reg. at 52,627. Specifically, the provisions that Plaintiffs challenge instruct arbitrators not to give weight to information they deem noncredible, not to give weight to information that is not related to the parties' offers, and not to give double weight to the same information when it is accounted for by multiple pieces of information. 45 C.F.R. § 149.510(c)(4)(iii)(E). The qualifying payment amount will always be relevant, and its credibility is

ensured through other statutory and regulatory mechanisms. *See* 42 U.S.C. § 300gg-111(a)(2), (a)(3)(E); 87 Fed. Reg. at 52,627; 45 C.F.R. § 149.140. Under the final rule, every piece of additional information before the arbitrator must be considered and evaluated for its credibility and relevance before the arbitrator gives it weight. These represent reasonable evidentiary and procedural rules that agencies are empowered to promulgate to govern adjudications, and which are entitled to deference. And none of them, either in isolation or in combination, reimposes a presumption in favor of the qualifying payment amount.

Plaintiffs rely on *American Corn Growers* for the proposition that the Departments unlawfully interfered with arbitrators' unfettered "discretion" to decide cases any way that they wish. TMA MSJ Mem. 22 (citing *Am. Corn Growers Ass'n v. EPA*, 291 F.3d 1 (D.C. Cir. 2002). But, as noted above, the statute assigns to the Departments, not to individual private arbitrators, the responsibility to "establish by regulation one independent dispute resolution process" to resolve payment disputes. 42 U.S.C. §§ 300gg-111(c)(2)(A). The Act therefore gives the Departments, not arbitrators, the responsibility to resolve any ambiguities with regard to the methodologies that an arbitrator should apply when selecting an offer. Thus, because there is a gap to fill in the Act concerning how to evaluate the various pieces of information that go into selecting payment amounts, the job of filling that gap belongs to the Departments that are charged with administering the Act, not private arbitrators. *See Martin v. Occupational Safety and Health Review Comm'n*, 499 U.S. 144, 152 (1991) (according deference to the agency with rulemaking authority, rather than a separate adjudicative body); *see also New York*, 969 F.2d at 1150; *Cent. Vt. Ry., Inc.*, 711 F.2d at 336; s*ee generally Am. Hosp. Ass'n v. NLRB*, 499 U.S. 606, 612 (1991) (recognizing agency authority to use rulemaking to establish "general principles to guide the required case-by-case . . . determinations").

Agency power to set processes for adjudications therefore includes the power to set necessary evidentiary rules to add consistency and predictability to those adjudications. It is well settled that an agency may establish evidentiary rules to govern administrative adjudications. *See, e.g.*, *Chem. Mfrs. Ass'n v. Dep't of Transp.*, 105 F.3d 702, 705 (D.C. Cir. 1997). Courts give "particular deference to an agency's promulgation of evidentiary rules governing its own adjudications." *Nat'l Min. Ass'n*, 292 F.3d at 868.

The fact that the arbitrators decide each individual payment dispute "does not prevent the [Departments] from supplanting the original discretionary chaos with some degree of order, and the principal instruments for regularizing the system of deciding . . . are classifications, rules, principles, and precedents." *Am. Hosp. Ass'n*, 499 U.S. at 612 (quoting K. Davis, Administrative Law Text § 6.04, p. 145 (3d ed. 1972)).

These rules promote the important "value in ensuring that all certified IDR entities approach payment determinations in a similar manner, which will promote consistency and predictability in the process, thereby lowering administrative costs and encouraging consistency in appropriate payments for out-of-network services." 87 Fed. Reg. at 52,627. This, in turn, will result in lowered administrative costs and encourage efficiency in resolving payment disputes. *See* 42 U.S.C. § 300gg-111(c)(3)(A) (stating congressional goals of "encouraging the efficiency" and "minimizing costs"). The Departments enacted these provisions of the final rule to ensure that the IDR process operates predictably for all parties regardless of which specific IDR entity is handling any particular dispute. *See* 87 Fed. Reg. at 52,627 ("Absent clear guidance on a process for evaluating the different factors, there would be no guarantee of consistency in how certified IDR entities reached determinations in different cases.").

As discussed above, protecting patients from surprise medical bills was a primary goal of the Act, but Congress also sought to address the spiraling cost of health care overall. Predictability and efficiency in the IDR process will have the effect of lowering the transaction costs of arbitrations that otherwise would be borne by patients in the form of higher premiums. *See* 86 Fed. Reg. at 55,996. A rule that promotes the consistency and predictability of the arbitration outcomes will thus encourage earlier settlements and further help to lower premiums, which has the benefit of both lowering health care costs for patients and reducing the federal deficit. *See* H.R. REP. NO. 116-615, at 58 (AR 335). Without a standardized IDR process, Congress's desire to create a low-cost, efficient means of dispute resolution, and its goal of lowering health care costs overall, would be thwarted. *See* 42 U.S.C. § 300gg-111(c)(3)(A) (Congress sought to "encourag[e] the efficiency" and "minimiz[e the] costs" of the arbitration process). The Act is designed to encourage voluntary dispute resolution and to minimize

the use of the IDR backstop by making arbitration outcomes more predictable. This is evident, for example, in the statutory provisions that prohibit the same two parties from re-litigating the same item or service twice within a 90-day period. *Id.* § 300gg-111(c)(5)(E)(ii). An unpredictable and standardless IDR process would work at cross-purposes to the Act.

Although the arbitrators are required by statute to consider the qualifying payment amount, *see id.* § 300gg-111(c)(5)(C)(i), the final rule does not prescribe any particular weight that should be given to that figure, consistent with this Court's decisions in *TMA I* and *LifeNet I*. *See* 87 Fed. Reg. 52,627 ("The Departments note that these final rules are not intended to impose a rebuttable presumption for payment determinations in the Federal IDR process."); *see also id.* ("The regulatory text in these final rules does not include the provisions that the District Court reasoned would have the effect of imposing such a presumption."). The qualifying payment amount is set by a complex formula established by regulations that Plaintiffs do not challenge here, subject to audits and penalties for noncompliance, and Congress mandated that this figure will always be a relevant factor for the arbitrator to consider. But the Departments have made clear that the final rule does not impose any obligation on the arbitrators to defer to the qualifying payment amount. *See, e.g.*, *id.* at 52,627-28 ("The Departments note that these final rules do not require certified IDR entities to default to the offer closest to the qualifying payment amount or to apply a presumption in favor of that offer."), *see also id.* ("[T]hese final rules do not require the certified IDR entity to select the offer closest to the [qualifying payment amount]. Rather, these final rules specify that certified IDR entities should select the offer that best represents the value of the item or service under dispute after considering the [qualifying payment amount] and all permissible information submitted by the parties."). Under the final rule, the parties are free to argue to the arbitrator that the qualifying payment amount is entitled to little, great, or even no weight at all and the arbitrator can accord the qualifying payment amount as much or as little weight as she concludes it deserves. *See id.* at 52,627 n.31 ("However, a provider or facility may always assert to the certified IDR entity that additional information points in favor of the selection of its offer as the out-of-network payment amount, even where that offer is for a payment amount that is different from the qualifying payment amount.").

1. The Final Rule Reasonably Instructs Arbitrators to Give Weight Only to Credible Information in Selecting the Offer that Best Represents the Value of the Qualified IDR Item or Service.

Plaintiffs now challenge, for the first time, a provision that the final rule carried over without change from the interim final rule that instructs the arbitrator to give weight only to information to the extent it is credible—in other words, that it is "worthy of belief and is trustworthy." 45 C.F.R. 149.510(a)(2)(v). As discussed above, Plaintiffs lack standing to challenge this provision, having failed to demonstrate that they intend to submit noncredible or untrustworthy information to arbitrators or intend for arbitrators to give weight to such information. *See, e.g.*, TMA MSJ Br. 22 ("surely arbitrators will not give weight to information they deem noncredible"). In addition, having neglected to raise this issue in their comments on the interim final rules—much less during prior rounds of litigation—Plaintiffs should not now be heard to complain. It is "well established that issues not raised in comments before the agency are waived." *Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 562 (D.C. Cir. 2002); *see Tex. Oil & Gas Ass'n v. EPA*, 161 F.3d 923, 933 n.7 (5th Cir. 1998) (finding challenges "were waived by [Plaintiffs'] failure to raise the objections during the notice and comment period"); *BCCA Appeal Grp. v. EPA*, 355 F.3d 817, 828 (5th Cir. 2003) (considering in the waiver analysis whether the Plaintiff "was a meaningful participant in the administrative proceedings" and "sufficiently clarified its position for the [agency]"). Here, the only Plaintiff that participated in the administrative process at all was TMA. During the comment stage for the first interim rule, TMA made a substantial submission, but that submission did not mention any concerns with the credibility standard. Letter from E. Linda Villarreal, President, Tex. Med. Ass'n, et al., to Xavier Becerra, Secretary, U.S. Dep't of Health & Human Servs., et al., at 16 (Sept. 7, 2021) (AR 7832). During the comment stage for the second interim rule, TMA signed onto two other submissions, neither of which raised those concerns either. At this point, Plaintiffs' belated complaints about the credibility standard are essentially "'an afterthought, brought forward at the last possible moment to undo the administrative proceedings,'" *In re DBC*, 545 F.3d 1373, 1378 (Fed. Cir. 2008), and this Court should find them waived. However, if this Court reaches the merits of this claim, it should find that the final rule reasonably instructs arbitrators to give weight only to credible information, and that the Departments were well within

their authority to issue such a reasonable rule.

By issuing a rule instructing arbitrators to give weight only to "credible" information—that is, information that "is worthy of belief and is trustworthy," 45 C.F.R. § 149.510(a)(2)(v), the Departments have acted well within their regulatory authority to promulgate reasonable evidentiary rules to govern IDR proceedings. The rule does not, as Plaintiffs suggest, instruct arbitrators to entirely ignore or not to consider information that is untrustworthy or incredible. As the final rule makes clear, the arbitrator must at least *consider* all the information before her, so long as the information does not relate to the prohibited categories of information described in 42 U.S.C. § 300gg-111(c)(5)(D) and 45 C.F.R. § 149.510(c)(4)(v). *See id.* § 149.510(c)(4)(iii)(B) ("The certified IDR entity must then consider . . . ."); *see id.* § 149.510(c)(4)(iii)(C) ("The certified IDR entity must also consider . . . ."); *see id.* § 149.510(c)(4)(iii)(D) ("The certified IDR entity must also consider . . ."). But the final rule reasonably instructs arbitrators to ultimately not give weight to information that is noncredible or untrustworthy. And while the qualifying payment amount is not subject to recalculation during the course of an arbitration, its credibility is separately tested; unlike the information submitted by the parties relating to the offers or the statutory factors under subsections (B)(i)(II), (B)(ii), and (C)(ii), the qualifying payment amount is governed by separate statutory and regulatory requirements, subject to audits and penalties, that are designed to provide indicia of credibility. *See* 45 C.F.R. § 149.140. Moreover, either party to an arbitration may raise any argument it wishes to contend that the qualifying payment amount does not represent the fair value of a given item or service. *See* 87 Fed. Reg. at 52,627.

By imposing rules that adopt a consistent methodology for the evaluation of information in the IDR process, and guiding arbitrators to evaluate information to determine whether it is worthy of belief and trustworthy before the arbitrator decides how much weight to give the information, the final rule promotes the interests of consistency and predictability that will benefit both parties and, ultimately, patients. Finally, Plaintiffs do not contend, nor could they, that an arbitrator's failure to give weight to noncredible or untrustworthy information harms them or will interfere with the arbitrator's ultimate obligation to select the offer that best represents the value of the item or service at issue.

2. The Final Rule Reasonably Instructs Arbitrators to Give Weight Only to Information That Relates to a Party's Offer in Selecting the Offer that Best Represents the Value of the Qualified IDR Item or Service.

The final rule likewise permissibly instructs arbitrators not to give weight to information that does not relate to the task before the arbitrator: selecting the offer that best represents the value of the item or service. Plaintiffs contend that 45 C.F.R. § 149.510(c)(4)(iii)(E) improperly imposes a heightened "related to" requirement for the categories of information listed in the statutory factors when the information in those factors will *always* relate to the parties' offers. TMA MSJ Mem. 23. But Plaintiffs misread the statute. In order for a party to submit any information to the arbitrators, it must relate to the offer, as required by 42 U.S.C. § 300gg-111(c)(5)(B)(ii). This "related to" requirement applies to the categories of information in the statutory factors, because it applies to all information submitted to the arbitrator: the parties "may each submit to the certified IDR entity with respect to such determination any information relating to such offer submitted by either party, including information relating to any circumstance described in subparagraph (C)(ii)." 42 U.S.C. § 300gg-111(c)(5)(B)(ii). The statute requires that any information submitted must, as a precondition, "relat[e] to such offer" and then goes on to explain that information that relates to an offer may include information relating to the statutory factors listed in subparagraph (C)(ii). The most natural reading of the statute is that the statutory factors listed are examples of types of information that may "relat[e] to such offer" but not a mandate that those categories of information will always relate to every offer.

But in any event, any dispute over the best reading of the statute is immaterial, because Plaintiffs do not actually contend that the arbitrator should be basing her decision on information that has no bearing on the dispute before her. The Departments explained that information submitted by a party or requested by an arbitrator "would be information relating to a party's offer if it tends to show that the offer best represents the value of the item or service under dispute." 87 Fed. Reg. at 52,628. The ultimate standard guiding the arbitrator's determination is that the arbitrator must select the offer that best represents the value of the qualified IDR item or service. 45 C.F.R. 149.510(c)(4)(ii)(A). Information relating to the offer in this context simply means information that bears on the ultimate determination that the arbitrator is tasked with making. Under the final rule, any

information the parties submit to the arbitrator—whether that information was requested by the arbitrator, submitted voluntarily by the parties, or submitted by the parties because it relates to the statutory factors—must always be considered by the arbitrator, but unless it relates to the offers that the arbitrator is deciding between, it should not be accorded weight in the arbitrator's determination. The instruction to give weight only to information that is relevant to the task at hand does not place a thumb on the scale of the qualifying payment amount. Indeed, Plaintiffs do not contend that the qualifying payment amount will ever not be relevant to the parties' offers.

It is not difficult to conjure examples where parties submit information that may relate to the statutory factors and yet has no bearing on which offer best represents the value of the item or service provided. In some instances, a provider's training and experience may have no bearing on the services rendered to a patient where the patient needed basic or routine medical care. For example, a physician's training such as advanced degrees or high academic honors might have no relation to the services that provider rendered to a patient where the patient merely needed a few stitches to treat a simple wound.

If the information submitted by a party is irrelevant to the ultimate determination, the arbitrator should, reasonably, give it no weight. Again, Plaintiffs do not take issue with (or even mention) the ultimate standard in the final rule that the arbitrator should select the offer that best represents the value of the item or service. The final rule simply provides the arbitrator with common-sense guidance that information is relevant if it "relates to" the ultimate question that the arbitrator is tasked with deciding. If information does not relate to which offer best represents the value of the item or service, it should have no bearing on the arbitrator's ultimate selection of an offer.

3. The Final Rule Reasonably Instructs Arbitrators to Avoid Weighing the Same Information Twice When Selecting the Offer that Best Represents the Value of the Qualified IDR Item or Service.

Plaintiffs also challenge the portions of the final rule that instruct arbitrators not to double-count information. In guiding the arbitrators towards selecting the offer that best represents the value of the qualified IDR item or service, the final rule explains "the certified IDR entity should not give weight to information to the extent . . . it is already accounted for by the qualifying payment amount . . . or other credible information." 45 C.F.R. § 149.510(c)(4)(iii)(E). The final rule does not, contrary

to Plaintiffs' contention, require arbitrators to "ignore information if it is accounted for in the qualifying payment amount." TMA MSJ Mem. 21. The final rule requires the arbitrators to consider all of the permissible information submitted, not to ignore anything. The purpose of this provision is, as the Departments explained, "to avoid *weighting* the same information twice." 87 Fed. Reg. at 52,628.

The final rule's instruction that arbitrators should not give double weight to any piece of information does not amount to a presumption in favor of the qualifying payment amount. In fact, the admonition against double-counting applies to any information submitted by the parties, not just the qualifying payment amount. *See id.* ("the certified IDR entity should evaluate the information and should not give weight to that information if it is already accounted for by any of the other information submitted by the parties"). And it is consistent with the statutory requirement to consider all the information relating to an offer submitted by either party, including information pertaining to the statutory factors described in § 300gg-111(c)(5)(C)(ii) and within the Departments' regulatory authority to prescribe order to the decisionmaking process, *see Am. Hosp. Ass'n*, 499 U.S. at 612. Because arbitrators are instructed to select the offer that best represents the value of the item or service, it is only logical that affording double weight to one piece of information would skew the arbitrator's assessment away from the true value, and towards whatever information was given outsized weight. This portion of the final rule thus avoids giving excessive weight to any single factor and is consistent with this Court's opinions in *TMA I* and *LifeNet I* holding that no single factor should be given outsized weight.

Because the qualifying payment amount already accounts for many pieces of important information that may be relevant to determining which offer best represents the value of the qualified IDR item or service, it may often be the case that double-counting comes up in the context of information that is already included in the qualifying payment amount. *See* 87 Fed. Reg. at 52,628. Recall that the qualifying payment amount is generally defined, for any given medical service, as "the median of the contracted rates recognized" by the insurer or group health plan, measured with respect to the payment rates for "the same or a similar item or service that is provided by a provider in the same or similar specialty and provided in the geographic region in which the item or service is

furnished," under all of the plans offered by that insurer or group health plan in a given insurance market. 42 U.S.C. § 300gg-111(a)(3)(E)(i)(I). The arm's-length negotiations underlying these contracted rates, ordinarily, would have taken into account things like the typical provider's level of training and experience. *Id.* §§ 300gg-111(c)(5)(C)(ii); 300gg-112(b)(5)(C)(ii). Likewise, one would expect these negotiations to take into account the insurer's or group health plan's market share in a given region; the typical acuity of patients receiving a service, or the complexity of that service; and any other features of providers that might be relevant in setting an arm's-length price. *See id.* §§ 300gg-111(c)(5)(C)(ii); 300gg-112(b)(5)(C)(ii).

For example, although one of the statutory factors that arbitrators must consider is the acuity of the patient, many billing codes already reflect the patient's acuity. Thus, the arbitrator in that situation would not need to give *additional* weight to information submitted by the parties showing that the patient was high acuity, but not unusually high acuity, when that information is already accounted for in a billing code specific to a high-acuity patient and already factored into the qualifying payment amount. However, the double-counting rule does not apply only to double-counting information contained in the qualifying payment amount. Example 4 in the final rule describes a scenario in which a facility's case mix and scope of services is already accounted for in the information submitted regarding prior contracted rates. 45 C.F.R. § 149.510(c)(iv)(D)(2). Neither of these pieces of information is necessarily accounted for by the qualifying payment amount, yet the final rule instructs that the arbitrator should consider all the information and give the information weight only once.

The prohibition on double-counting information is consistent with the arbitrator's ultimate responsibility—to select the offer that best represents the value of the item or service. *See* 87 Fed. Reg. at 52,629. If one piece of information is submitted twice, the second time that information is submitted does not add anything of probative value to the arbitrator. The double-counting rule likewise does not prohibit parties from arguing that some piece of information has not been adequately accounted for in the qualifying payment amount or in any other piece of information. But if an arbitrator gives double or even triple weight to the same piece of information over and over again, the arbitrator's selection of an offer will be skewed by that double or triple counting and the double- or triple-counted

information will receive unwarranted weight in the arbitrator's selection. This portion of the final rule is thus designed to prevent "the selection of an offer that does not best represent the value of the qualified IDR item or service." 87 Fed. Reg. at 52,629.

The final rule also instructs arbitrators to explain in their written decisions what information the arbitrator determined demonstrated that the offer selected best represented the value of the item or service, to explain the weight given to the qualifying payment amount and any additional credible information, and to explain, if the arbitrator relied on any of the categories of additional information, why the arbitrator concluded that the information was not already reflected in the qualifying payment amount. 45 C.F.R. § 149.510(c)(4)(iv)(B). Plaintiffs argue that this written decision requirement "disincentivizes arbitrators from giving weight to any information other than the [qualifying payment amount]." TMA MSJ Mem. 22. But Plaintiffs' imputation of bad faith and laziness to the arbitrators is unwarranted. The Act requires the Departments to publish a report for each calendar quarter that states, among other things, "the number of times the payment amount determined (or agreed to) under this subsection exceeds the qualifying payment amount, specified by items and services," and for each dispute decided by an arbitrator, "the amount of such offer so selected expressed as a percentage of the qualifying payment amount[.]" 42 U.S.C. §§ 300gg-111(c)(7)(A)(v), (B)(iv). The written decision assists the Departments in tracking this information. Likewise, the Departments have an interest in understanding how the arbitrators view the qualifying payment amount and whether the arbitrators find that the qualifying payment amount regularly fails to account for important information. *See* 87 Fed. Reg. at 52,626. By understanding how the arbitrators take into account and weigh the qualifying payment amount, the Departments can not only effectuate their reporting requirements mandated by Congress, but also evaluate whether any updates or changes to qualifying payment amount disclosures are needed. *Id.*

B. The Rule is Not Arbitrary and Capricious for Not Allowing Arbitrators to Investigate the Accuracy of the Qualifying Payment Amount.

Plaintiffs allege that the final rule conflicts with the Act and is arbitrary and capricious because it requires arbitrators to evaluate the relevance and credibility of additional information submitted by

the parties to the arbitrator but does not similarly require the arbitrator to evaluate the relevance and credibility of the qualifying payment amount, which they claim fails to account for what they allege are persistent problems in the calculation of the qualifying payment amount. They argue that this also amounts to a presumption in favor of the qualifying payment amount. But prohibiting the arbitrator from delving into an investigation or re-calculation of the qualifying payment amount does not presume that the qualifying payment amount best represents the value of the item or service. Rather, it reflects an attempt to lower transaction costs for the disputing parties while at the same time reserving to the Departments, not the arbitrators, the ultimate responsibility of auditing and monitoring the accuracy of the qualifying payment amounts. 42 U.S.C. § 300gg-111(2)(A)(I).[9] And it promotes the primary purpose of the Act—providing clarity to patients on their financial liability and preventing unpleasant surprises.

This approach does not reimpose a presumption in favor of the qualifying payment amount and is not arbitrary and capricious. The Departments reasonably concluded that an investigation into the accuracy and reliability of the qualifying payment amount during the IDR process would add unnecessary, costly, and time-consuming burdens to the arbitrators. Unlike other information submitted by the parties, the qualifying payment amount is governed by statutory and regulatory requirements that already provide some indicia of relevance and credibility. See 45 C.F.R. § 149.140; 87 Fed. Reg. at 52,627 (qualifying payment amount "meet[s] the same credibility standard . . . through other mechanisms"). As the Departments explained, "to the extent the [qualifying payment amount] is calculated in a manner that is consistent with the detailed rules issued under the July 2021 interim final rules, and is communicated in a way that satisfies the applicable disclosure requirements, the [qualifying payment amount] will meet the credibility requirement that applies to the additional information and circumstances set forth in these final rules." 87 Fed. Reg. at 52,627. Likewise, the arbitrator need not separately evaluate whether the qualifying payment amount "relates to" the offers

[9] Although Plaintiffs, particularly LifeNet, appear to disagree with the way the qualifying payment amount is calculated and audited, LifeNet MSJ Mem. 9-10, they do not challenge those portions of the regulations governing the calculation or auditing of the qualifying payment amount.

because the qualifying payment amount will always relate to the offers. *Id.* This is so not only because the qualifying payment amount is designed to represent a rough proxy for the fair market value of the item or service, and thus is directly relevant to determining the value of the item or service, but also because Congress determined that the qualifying payment amount was relevant and accordingly required the arbitrator to consider it in every instance. *See* 42 U.S.C. § 300gg-111(c)(5)(C)(i). And the parties are always free to argue to the arbitrator that the qualifying payment amount does not represent the best value of the item or service at issue in the dispute. If the arbitrator finds that parties have successfully cast doubt on whether the qualifying payment amount represents the appropriate out-network-payment amount, the arbitrator can select whichever offer she thinks best represents the value of the service, even if that offer is not the closest to the qualifying payment amount.

Allowing the arbitrator to re-open the calculation of the qualifying payment amount would also frustrate the primary purpose of the Act—as the name suggests, the purpose of the No Surprises Act is first and foremost to eliminate the unpleasant "surprises" that patients face from high costs associated with receiving certain out-of-network care. The qualifying payment amount is a central feature of the Act separate and apart from the IDR process. When a patient receives medical care subject to the Act's surprise billing provisions, the qualifying payment amount immediately comes into play in setting the patient's cost-sharing obligations. *See* 42 U.S.C. 300gg-111(a)(3)(H). Although Congress provided for the qualifying payment amount to play a role in several aspects of the new processes effected by the Act, the first and most critical role of the qualifying payment amount is to establish upfront the financial obligations on patients, so that they face "no surprises" in medical bills stemming from out-of-network care covered by the Act. By the time an arbitrator is considering the qualifying payment amount in selecting an out-of-network payment amount, the qualifying payment amount has already been essential in setting a patient's financial liabilities. Opening up the re-calculation of the qualifying payment amount at this late stage in the payment process would potentially open patients up to surprise and unpredictable medical bills once again, frustrating the very purpose of the Act.

Allowing an arbitrator to conduct a full-blown discovery into the accuracy of the qualifying payment amount would likewise derail what Congress intended to be an efficient dispute resolution process that would pass savings on to parties and patients through lowered transaction costs. It also runs counter to the Act, which placed the responsibility for auditing the qualifying payment amount with the Departments, not the individual arbitrators. 42 U.S.C. § 300gg-111(a)(2)(A)(i). The rule furthers the Congressional purpose for the Act's independent dispute resolution mechanism to "reduce premiums and the deficit," H.R. REP. NO. 116-615, at 58 (AR 335), a goal that could only be accomplished if that mechanism were structured to facilitate a streamlined and efficient arbitration process, *see id.* at 57 (AR 334). While there will always be some administrative costs incurred in the arbitration process, "[i]f those administrative costs are high enough, they could undermine the effectiveness of the [Act.]" *Examining Surprise Billing: Protecting Patients from Financial Pain: Hearing Before the H. Comm. On Educ. And Labor, Subcomm. On Health, Employment, Labor and Pensions*, 116th Cong. 8 (2019) (statement of Christen Linke Young, Brookings Inst.) (AR 460).

In formulating the final rule, the Departments sought to promote transparency into the calculation of the qualifying payment amount while at the same time minimizing administrative burdens on health plans and issuers and on the Federal IDR process. "The Departments sought to balance those competing interests by, on the one hand, requiring plans and issuers to make certain disclosures with each initial payment or notice of denial of payment and to provide certain additional information upon request . . . and, on the other hand, avoiding more wide-reaching disclosure requirements that could add to the costs and burdens of adjudicating claims." 87 Fed. Reg. at 52,625. And the Departments continue to consider comments about whether additional disclosures related to the qualifying payment amount calculation methodology should be required. *Id.* at 52,626.

By lowering transaction costs for resolving out of network payment disputes, the Act sought to pass those savings along to providers, insurers, group health plans, patients, and the federal government. The final rule is essential to furthering that congressional objective in providing an efficient and low-cost dispute resolution mechanism and providing immediate clarity to patients on their financial obligations.

C. The Rule is Not Arbitrary and Capricious for Instructing Arbitrators to Consider the Qualifying Payment Amount First.

Plaintiffs claim the final rule is arbitrary and capricious because it instructs the arbitrators to consider the qualifying payment amount and "then" consider the additional information submitted by the parties. 45 C.F.R. § 149.510(c)(4)(iii)(B). Although Plaintiffs fault the Departments for structuring this analysis to begin with the qualifying payment amount, the Act itself is structured the same way. The statute lists the qualifying payment amount as the first factor for the arbitrator's consideration; the other factors listed for the arbitrator to consider are described as "additional circumstances" or "additional information." 42 U.S.C. §§ 300gg-111(c)(5)(C)(i)(II), (ii). These circumstances could only be "additional," of course, if there were some other circumstances already in place that they could be added to—here, the qualifying payment amount. The statute thus textually informs the reader that the analysis should begin with the qualifying payment amount, and then should move on to take into account the other statutory factors. *See In re Border Infrastructure Envtl. Litig.*, 915 F.3d 1213, 1223 (9th Cir. 2019) ("In simple terms, 'additional' means 'supplemental.'"). And the qualifying payment amount is the only information that is a given in every single arbitration—the parties may choose not to submit additional information relating to the offer or relating to certain of the statutory factors, but the qualifying payment amount will *always* be present for the arbitrator to consider. *See* 87 Fed. Reg. at 52,627. It thus makes sense for the final rule to simply mirror the statute and to instruct arbitrators to begin with the qualifying payment amount, since it will always be present in the IDR process, and then move on to the "additional information."

At any rate, Plaintiffs rely on nothing more than armchair psychology to suggest that the order of operations caused by the inclusion of a single word—"then"—will have any impact on the offer that the arbitrator ultimately selects. Plaintiffs argue that the arbitrator's view will be forever tainted by having considered the qualifying payment amount first, TMA MSJ Mem. 20, despite the fact that, as discussed above, the final rule nowhere requires the arbitrator to give more weight or defer to the qualifying payment amount, and in fact expressly disclaims any such instruction. The final rule instructs the arbitrator to select the offer that best represents the value of the item or service, and whether the arbitrator considers the qualifying payment amount first or the provider's level of training

and experience first, or the teaching status of the facility first has no bearing on which offer the arbitrator should ultimately select under the final rule. Whether the arbitrator considers the qualifying payment amount first or last, the final rule makes clear that the arbitrator should select whichever offer best represents the value of the item or service.

IV. Any Relief Should be Appropriately Limited.

In the event the Court agrees with Plaintiffs, consistent with the jurisdictional constraints of Article III and the traditional equitable power of the Court, any relief should be limited—indeed, any relief should be no broader than necessary to remedy the demonstrated harms of the specific, identified Plaintiffs in this case. "The Court's constitutionally prescribed role is to vindicate the individual rights of the people appearing before it." *Gill v. Whitford*, 138 S. Ct. 1916, 1933 (2018). So "[a] plaintiff's remedy must be tailored to redress the plaintiff's particular injury," *id.* at 1934, and "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs," *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (quoting *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979)). Plaintiffs' invocation of the APA does not justify a departure from these principles. Nothing in the APA's directive to "set aside" unlawful "agency action" mandates that "agency action" shall be set aside globally, rather than as applied to the plaintiffs. 5 U.S.C. § 706(2). And Congress enacted the APA against the background rule that statutory remedies should be construed in accordance with "traditions of equity practice." *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944). Moreover, any relief should be limited to the particular provisions, if any, that are found to be invalid. *See K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988) (severing provisions of a regulation found to be invalid).

Plaintiffs' request that the Court should "vacate the challenged provisions of the final rule and remand with . . . instructions" is inappropriate. TMA MSJ Mem. 30 (citation omitted). That request functionally seeks an injunction, which would require Plaintiffs to meet a stringent standard that they have certainly not met here. "Unlike a district court managing a 'garden variety civil suit,' a district

court reviewing a final agency action" under the APA "'does not perform its normal rule' but instead 'sits as an appellate tribunal.'" *Palisades Gen. Hosp. Inc., v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005). Thus, under settled principles of administrative law, when a "court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with the correct legal standards." *Id.* Relief in an APA case is therefore ordinarily "limited only to vacating the unlawful action," and courts should not enjoin an agency to implement a specific remedy that "preclude[es] future agency decisionmaking." *Hill Dermaceuticals v. FDA*, 709 F.3d 44, 46 n.1 (D.C. Cir. 2013), as Plaintiffs effectively request here.

At most, the Court should remand the matter to the Departments without vacatur of the challenged provisions. Vacatur would be highly disruptive, as it would leave arbitrators with no guidance as to how to proceed with their decision-making. Arbitrations are already underway, and without guidance, face the risk of becoming unpredictable and costly to the parties involved. These costs would ultimately be passed along to patients, frustrating Congress's goal of protecting patients and lowering health care costs. These interests counsel heavily against vacatur. *See Cent. & S.W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000).

CONCLUSION

For the foregoing reasons, the Defendants' motion for summary judgment should be granted, and the Plaintiffs' motion for summary judgment should be denied.

Dated: November 9, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify on this 9th day of November, 2022, a true and correct copy of this document was served electronically by the Court's CM/ECF system to all counsel of record.

/s/ Anna Deffebach
ANNA DEFFEBACH